



294

1645  
MAY 21 2002  
TECH CENTER 160012900

PTO/SB/21 (08-00)  
Approved for use through 10/31/2002. OMB 0851-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paper Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b> <small>(to be used for all correspondence after initial filing)</small>	Application Number	10/056,908	
	Filing Date	Jan 25, 2002	
	First Named Inventor	Hinkel, Christopher	
	Group Art Unit	1845	
	Examiner Name	Unknown	
Total Number of Pages in This Submission	6	Attorney Docket Number	TM0141-UT

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	PTO form 1449 -3 pgs. <del>incomplete</del> plus 40 references.
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	Stamped Return postcard
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s)	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application	Remarks	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	James E. Butler Reg. No. 40,931	Customer No. 29748
Signature		
Date	May 16, 2002	

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date: May 16, 2002			
Type or printed name	Cassandra Peters		
Signature		Date	May 16, 2002

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



TM014  
PATENT

RECEIVED  
MAY 21 2002  
TECH. CENTER (180/2900)

MAY 21 2002

RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group A Unit 645

Application of Hinkel et al.

Confirmation No. 2363

Serial No. 10/056,908

Filed January 25, 2002

For METHODS OF ANALYSIS OF NUCLEIC ACIDS

May 16, 2002

INFORMATION DISCLOSURE STATEMENT

TO THE COMMISSIONER OF PATENTS,

SIR:

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, Applicants enclose copies of the references listed on the attached PTO Form 1449 (modified) for consideration by the Patent and Trademark Office and to be made of record in the above-entitled application.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. 1.97(b) in that Applicants believe that it is being filed before the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. 1.97(c) is required. If Applicants are mistaken, and the mailing date of the first Office action on the merits precedes the filing of this Information Disclosure Statement, Applicants authorize that the fee due under 37 C.F.R. 1.17(p) be charged to Deposit Account No. 50-2021.

Respectfully submitted,

James E. Butler, Ph.D., Reg. No. 40,931  
TORREY MESA RESEARCH INSTITUTE  
3115 Merryfield Row  
San Diego, CA 92121  
(858) 812-1260

Page 1 of 2



TM0141-UT  
PATENT

**CERTIFICATE OF MAILING**

I hereby certify that the foregoing Information Disclosure Statement in the application of Hinkel et al., Serial No. 10/056,908, filed January 25, 2002, is being deposited with the United States Postal Service as first class mail, postage pre-paid, and addressed to: Commissioner for Patents, Washington, D.C. 20231 on this 16th day of May, 2002.

Cassandra Peters  
Cassandra Peters

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet **3** of **3****Complete if Known**

Application Number	10/056,908
Filing Date	1/25/2002
First Named Inventor	Hinkel et al.
Group Art Unit	1645
Examiner Name	Unknown
Attorney Docket Number	TM0141-UT

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
AL		LIU et al., "Overlapping PCR for bi-directional PCR amplification of specific alleles: a rapid one-tube method for simultaneously differentiating homozygotes and heterozygotes." <u>Genome Res.</u> , 7:389-398, (1997).	
AM		NEWTON et al., "Analysis of any point mutation in DNA: The amplification refractory mutation system (ARMS)." <u>Nuc. Acids Res.</u> , 17(7):2503-2516, (1989).	✓
AN		NICHOLS et al., "Direct sequencing of the gene for Maryland/German familial amyloidotic polyneuropathy Type II and genotyping by allele-specific enzymatic amplification." <u>Genomics</u> , 5:535-540, (1989).	✓
AO		SAMIOTAKI et al., "Dual-color detection of DNA sequence variants by ligase-mediated analysis." <u>Genomics</u> , 20:238-242, (1994).	✓
AP		SHUMAKER et al., "Mutation detection by solid phase primer extension." <u>Human Mut.</u> , 7:346-354, (1996).	✓
AQ		SMITH et al., "A rapid, sensitive, multiplexed assay for detection of viral nucleic acids using the FlowMatrix system." <u>Clin. Chem.</u> , 44(9):2054-2056, (1998).	✓
AR		SOMMER et al., "A novel method for detecting point mutations or polymorphisms and its application to population screening for carriers of phenylketonuria." <u>Mayo Clin. Proc.</u> , 64:1361-1372, (1989).	✓
AS		SYVÄNEN et al., "Identification of individuals my analysis of biallelic DNA markers, using PCR and solid-phase minisequencing." <u>Am. J. Hum. Genet.</u> , 52:46-59, (1993).	✓
AT		WU et al., "Allele-specific enzymatic amplification of $\beta$ -globin genomic DNA for diagnosis of sickle cell anemia." <u>Proc. Natl. Acad. Sci. USA</u> , 86:2757-2760, (1989).	✓
AU		ZIPFEL et al., "Complexity of the primary genetic response to mitogenic activation of human T cells." <u>Mol. Cell. Biol.</u> , 9(3): 1041-1048, (1989).	✓
AV			

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Unique citation designation number. \*Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patent, Washington, DC 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3**Complete if Known**

Application Number	10/056,908
Filing Date	1/25/2002
First Named Inventor	Hinkel et al.
Group Art Unit	1645
Examiner Name	Unknown
Attorney Docket Number	TM0141-UT

RECEIVED  
MAY 21 2002  
CENTER 1600/2900

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AA	BARANY et al., "Genetic disease detection and DNA amplification using cloned thermostable ligase." <i>Proc. Natl. Acad. Sci. USA</i> , 88:189-193, (1991).	
	AB	BRAY et al., "High-throughput multiplex SNP genotyping with MALDI-TOF mass spectrometry: Practice, Problems and Promise." <i>Hum. Mutat.</i> , 17:296-304, (2001).	
	AC	CHEN et al., "A homogeneous, ligase-mediated DNA diagnostic test." <i>Genome Res.</i> , 8:549-556, (1998).	
	AD	CHEN et al., "Fluorescence energy transfer detection as a homogeneous DNA diagnostic method." <i>Proc. Natl. Acad. Sci. USA</i> , 94:10756-10761, (1997).	
	AE	DAY et al., "Detection of steroid 21-hydroxylase alleles using gene-specific PCR and a multiplexed ligation detection reaction." <i>Genomics</i> , 29:152-162, (1995).	✓
	AF	DAY et al., "Electrophoresis for genotyping: Microtiter array diagonal gel electrophoresis on horizontal polyacrylamide gels, hydrolink, or agarose." <i>Anal. Biochem.</i> , 222:369-395, (1994).	✓
	AG	GRAVES, D., "Powerful tools for genetic analysis come of age." <i>Trends Biotechnol.</i> , 17:127-134, (1999).	✓
	AH	GROSSMAN et al., "High-density multiplex detection of nucleic acid sequences: oligonucleotide ligation assay and sequence-coded separation." <i>Nuc. Acids Res.</i> , 22(21):4527-4534, (1994).	✓
	AI	HSU et al., "Genotyping single-nucleotide polymorphisms by the invader assay with dual-color fluorescence polarization detection." <i>Clin. Chem.</i> , 47(8):1373-1377, (2001).	✓
	AJ	KOYAMA et al., "Structure of a cytotoxic T-lymphocyte-specific gene shows a strong homology to fibrinogen $\beta$ and $\gamma$ chains." <i>Proc. Natl. Acad. Sci. USA</i> 84:1609-1613, (1987).	✓
	AK	LANDEGREN et al., "A ligase-mediated gene detection technique." <i>Science</i> , 241:1077-1080, (1988).	✓

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

## **Complete if Known**

Application Number	10/056,908
Filing Date	1/25/2002
First Named Inventor	Hinkel et al.
Group Art Unit	1645
Examiner Name	Unknown
Attorney Docket Number	TM0141-UT

RECEIVED  
 MAY 21 2002  
 ECH CENTER 1600/2900

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	1	5,324,631		Helentjaris et al.	06/28/1994	
	2	5,459,037		Sutcliffe et al.	10/17/1995	
	3	5,645,995		Kieback	07/08/1997	
	4	5,695,937		Kinzler et al.	12/09/1997	
	5	5,712,126		Weissman et al.	01/27/1998	
	6	5,830,711		Barany et al.	11/03/1998	
	7	5,834,181		Shuber	11/10/1998	
	8	5,846,710		Bajaj	12/08/1998	
	9	5,866,330		Kinzler et al.	02/02/1999	
	10	5,871,697		Rothberg et al.	02/16/1999	
	11	5,888,819		Goelet et al.	03/30/1999	
	12	5,925,517		Tyagi et al.	07/20/1999	
	13	5,945,283		Kwok et al.	08/31/1999	
	14	5,962,233	With- drawn	Livak et al.	10/05/1999	
	15	6,150,095		Southern et al.	11/21/2000	
	16	6,268,222	B1	Chandler et al.	07/31/2001	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	1*
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	17	PCT	WO 98/51789	A2& A3	Display Systems Biotech	11/19/1998	
	18	PCT	WO 99/37814	A1	Luminex Corporation	07/29/1999	
	19	PCT	WO 01/13120	A1	Luminex Corporation	02/22/2001	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.